

Remarks

I. Status of the Claims

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 45, 49 and 52-56 are pending in the application, with claims 45 and 53 being the independent claims.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. Summary of the Office Action

In the Office Action dated September 9, 2003, the Examiner has withdrawn claims 59-92 from consideration due to an alleged constructive election, and has made one rejection of the claims. Applicants respectfully offer the following remarks concerning each of these elements of the Office Action.

III. The Withdrawal of Claims 59-92

In the Office Action at pages 2-3, the Examiner has withdrawn claims 59-92 from consideration. In making this withdrawal, the Examiner alleges that these claims are directed to an invention distinct from that of claims 45, 49 and 52-56 that was allegedly constructively elected by original presentation for prosecution on the merits. *See* Office Action at page 3, lines 5-9. Applicants respectfully traverse the withdrawal of claims

59-92 from consideration. However, for reasons unrelated to this withdrawal, claims 59-92 have been cancelled, without prejudice to or disclaimer of the subject matter encompassed therein. Applicants reserve the right to prosecute the subject matter of the claims in one or more continuing applications.

IV. Rejection under 35 U.S.C. § 103(a)

In the Office Action at pages 3-7, the Examiner has rejected claims 45, 49 and 52-56 under 35 U.S.C. §103(a) as being unpatentable over Todd (WO 96/32500) in view of Sobol *et al.* (U.S. Patent No. 5,543,296) and Isner (U.S. Patent No. 5,652,225). Applicants respectfully traverse this rejection.

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *See In re Piasecki*, 223 USPQ 785, 787-88 (Fed. Cir. 1984). In order to establish a *prima facie* case of obviousness, all of the elements of the claims must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Moreover, the Examiner can satisfy the requisite burden only by showing some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references in such a way as to produce the invention as claimed. *See In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

In the present case, the Examiner's burden has not been satisfied since a reason, suggestion or motivation is lacking in the cited references. Absent such suggestion and motivation, the references may not be properly combined to render the claimed invention

obvious. *See id.* Moreover, the teaching or suggestion required to properly combine the disclosures of cited references must be found in the prior art itself, not in the Applicants' disclosure. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In view of these legal prerequisites under 35 U.S.C. §103, Applicants respectfully assert that a *prima facie* case of obviousness cannot be established with respect to the pending claims based on the cited references.

The Examiner asserts that Todd discloses several reagents that are combined during preparation of the PCR reaction mixture, including a restriction endonuclease, anti-*Taq* polymerase antibodies, and multiple buffers. *See* Office Action at page 4. Although the Examiner admits that Todd "does not meet the requirements of the claims," she asserts that the "master mix" compositions disclosed in Sobol *et al.* and Isner *et al.* provide the necessary motivation to prepare a "master mix" that includes all PCR reagents other than primers and template to meet the requirements of Applicants' claims. *See* Office Action at page 4. Applicants respectfully disagree.

Applicants respectfully assert that Todd is fatally deficient as a primary reference for its failure to meet the limitations of Applicants' claims. As the Examiner herself admits, Todd does not disclose a composition that "does not contain any nucleic acid molecules" as is required by independent claims 45 and 53. *See* Office Action at page 4. These deficiencies in Todd are not cured by the disclosure of Sobol and Isner, which do not disclose, suggest, or otherwise contemplate the modification of the compositions of Todd in such a way as to result in the presently claimed compositions.

The Examiner's reliance upon Sobol *et al.* and Isner *et al.* to provide motivation to prepare the compositions of the present invention is misplaced in that it mistakenly

focuses on the preparation of a "master mix" of PCR reagents in both of these references. See Office Action at page 5. For example, the Examiner states that "[A]n ordinary artisan would have been motivated to have prepared a master mix including all reagents but template and primers in order to have possessed a single master mix composition that could be employed successfully with a variety of templates and primers, as exemplified by Sobol *et al.*, for the advantage of convenience and efficiency." See Office Action at page 5. Applicants contend, however, that Sobol *et al.* and Isner *et al.* were improperly considered by the Examiner as references to show obviousness, as their teachings are not relevant to the presently claimed invention. The Examiner stated in the Office Action of September 9, 2003, that "the Sobol *et al.* reference was not cited for any teaching of a composition including an endonuclease, but was cited for its teaching of a master mix comprising all reagents other than primers and template in the practice of PCR." See Office Action at page 7. The Examiner went on to state that "the Isner *et al.* reference was cited for its disclosure that the use of master mixes improves accuracy and reproducibility, not for any teaching of the particular reagents that would be included in a specific master mix (which would clearly depend on the nature of the reaction being performed.)" See *id.*

However, this focus on the preparation of a master mix in general loses sight of the elements of present invention as claimed. The present claims are not drawn to the concept of making such a "master mix," but instead to novel and nonobvious **compositions**. What makes the present invention nonobvious are the **components** of the compositions as claimed, not whether or not they are admixed prior to use. A mixture comprising such components simply is not disclosed or suggested in the cited references,

and one of ordinary skill in the art would not have been motivated to make and use the presently claimed compositions.

If one were to examine claims to compositions using the logic apparently used by the Examiner in the present rejection, compositions comprising *any* combination of more than one component would be held to be obvious if the components were mixed prior to use. For example, applying the Examiner's logic, a novel and nonobvious cell culture medium would not be patentable if prepared in a "master mix" prior to being added to petri dishes or plates, despite improved results or a new combination of ingredients, as long as each ingredient was known in the art, even if in separate references. Of course, this approach is contrary to the clear guidance of the Federal Circuit, which has held that there is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time the invention was made. *See Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1995). Instead, what is needed is a reason, suggestion, or motivation *in the prior art* that would motivate one of ordinary skill to combine the cited references, that would also suggest a reasonable likelihood of success in making or using the claimed invention as a result of that combination. *See In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) (emphasis added). As noted above, there simply is no reason, suggestion or motivation present in the cited art that would meet the *Fromson* and *Dow Chem. Co.* standards.

It therefore appears that the Examiner is attempting to use Applicants' own specification, rather than in the cited art, to find the motivation required to combine the cited references. As the Federal Circuit has held numerous times, however, such a

hindsight analysis is impermissible -- instead, the Examiner must show suggestions, explicit or otherwise, that would compel one of ordinary skill to combine the cited references in order to make and use the claimed invention. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) (“When prior art references require selective combination by the [fact-finder] to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.”); *Fine*, 5 USPQ2d at 1600 (“One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”); *In re Pleuddemann*, 910 F.2d 823, 828 (Fed. Cir. 1990) (noting that use of an applicant’s specification as though it were prior art to support an obviousness determination is legal error); *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (holding that both the suggestion to combine references, and a reasonable expectation of success in making the claimed invention, “must be founded in the prior art, not in the applicant’s disclosure”). The Board has also provided the same mandate on this issue:

[i]t is impermissible to use the claimed invention as an instruction manual or “template” to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious a rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis.

Ex parte Haymond, 41 USPQ2d 1217, 1220 (Bd. Pat. App. Int. 1996). Thus, the use of hindsight analysis in the present case is impermissible and cannot be used to attempt to

establish a *prima facie* case of obviousness. Accordingly, Applicants respectfully assert that a *prima facie* case of obviousness cannot be established with respect to Applicants' claims using the cited references.

Hence, the Examiner has failed to show that a person of ordinary skill in the art would have been motivated to prepare the presently claimed compositions based solely on information contained within the cited references.

Applicants have demonstrated above that the concept of master mixes alone does not provide motivation to combine elements from randomly selected prior art references, such as Sobol and Isner. Consequently, the Examiner is left with the Todd reference, which she has admitted does not meet the limitations of Applicants' claims. Applicants therefore respectfully request that the rejection under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Brian J. Del Buono", with a stylized flourish at the end.

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